

January 8, 1999

This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.



COMPLIANCE SERVICES INTERNATIONAL

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November 30, 1998

Ms. Lorilyn McKay, Chemical Review Manager
Reregistration Branch I, SRRD (7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

RECEIVED
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OPP PUBLIC DOCKET

Re: **Pirimiphos-Methyl (Case No. 2535)**

Dear Lori:

On behalf of Wilbur-Ellis Company, we are responding to your letter of October 28, 1998 requesting comments on errors, confidential business information (CBI), and planned data regarding your preliminary human health and ecological risk assessments for this organophosphate compound.

We have attached sheets that list the errors in 1) the "RED Chapter" dated April 13, 1998 from the Environmental Fate and Effects Division; and 2) the "Toxicology Chapter" dated May 18, 1998 from the Health Effects Division. We have also reviewed the "Product and Residue Chemistry Chapters" dated June 1, 1998 from the Health Effects Division and found no obvious errors, without being able to conduct a more extensive and expensive comparative analysis with the original studies.

We found no errors in the remaining documents for: 1) "Acute and Chronic Dietary Risk Analysis" dated July 21, 1998; 2) "HED Human Risk Assessment and Supporting Documentation" dated October 23, 1998; 3) "Conclusions of the Metabolism Assessment Review Committee" dated May 15, 1998; 4) "The ORE aspects" dated April 9, 1998; and 5) the "Report of the Hazard Identification Assessment Review Committee" dated January 29, 1998.

Except to the extent that product chemistry data is protected under FIFRA Section 10, we make no CBI claim for the data contained in the documents.

In regard to planned data, a timetable for toxicology data will be determined by December 31, 1998. In addition, we are waiting for instructions to analyze samples in a storage stability study under GLN 860.1380 that has been ongoing and near completion for the storage requirements. We previously supplied data from 4 months storage, and stated at that time our intentions for completing the study.

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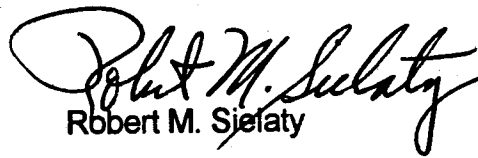
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CSI Letter of November 30, 1998

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We are providing an electronic version of this letter and supporting material, for your convenience. We will also submit any additional comments, as appropriate, within the next time frame. If there are any questions or concerns, please contact me immediately. Thank you.

Very truly yours,


Robert M. Sielaty

Attachments

cc: G. Dutto (Wilbur-Ellis)

ERRORS IN "RED CHAPTER FOR PIRIMIPHOS-METHYL"

Dated April 15, 1998

Environmental Fate and Effects Division

Page 1: EXECUTIVE SUMMARY

1. Use Characterization

This section incorrectly states that several million acres in the U.S. are planted each year with pirimiphos-methyl treated seeds. Less than 1% of the corn and sorghum seed are treated with pirimiphos-methyl. Based on 1993 sales figures previously provided to the Agency by the Sponsor **(See attached Usage Information)**, 550 pounds active ingredient were sold for use on bulk/bagged corn to be used for seed. This amount of pirimiphos-methyl would only treat approximately 6.9×10^7 pounds of seed or 0.014% of the estimated 4.88×10^{11} pounds of corn grown in 1993. Similarly, the sorghum values were 525 pounds of active ingredient sold, capable of treating 6.5×10^7 pounds of seed representing an estimated 0.16% of the 4.4×10^{10} pounds of sorghum produced in 1993.

This section also incorrectly states that the compound is available in a variety of formulations. Pirimiphos-methyl is only available as an emulsifiable concentrate and incorporated into plastic ear tags. There is a proposed use for a ready to use pour-on application for cattle. There are no registered dust, ULV sprays, aerosols, ready to use sprays or smoke generators in the United States.

2. Exposure Characteristics

Environmental Fate Assessment

This section incorrectly lists a number of uses for the compound. Pirimiphos-methyl is only used for post-harvest treatment of stored corn and sorghum grain and seed, as an ingredient in ear tags on beef and non-lactating cattle, and for indoor treatment of iris bulbs and their storage rooms.

Page 3 - ENVIRONMENTAL ASSESSMENT

1. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

i. Birds, Acute and Subacute

The table incorrectly lists the species in the Avian Acute Oral Toxicity Study as the Mallard Duck. This study was done with Northern Bobwhite (*Colinus virginianus*).

ii. Birds, Chronic

There is no evidence that birds may be subject to repeated exposure to the pesticide. The seed is treated at the beginning of storage and there is no active control of insects at planting time.

There is no evidence of reproductive effects from the organophosphate, pirimiphos-methyl. The field studies conducted with another pesticide were conducted with heptachlor, a banned organochlorine pesticide of an entirely different class of pesticides than pirimiphos-methyl.

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c. Toxicity to Plants

Pirimiphos-methyl is misspelled in the last sentence of the first paragraph.

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4. Data Gaps

There is no evidence that birds may be subject to repeated exposure to the pesticide since the seed is treated at the beginning of storage and there is no active control of insects at planting time.

There is no evidence of reproductive effects from the organophosphate, pirimiphos-methyl. The field studies conducted with another pesticide were conducted with heptachlor a banned organochlorine pesticide of an entirely different class of pesticides than pirimiphos-methyl.

**ERRORS IN "PIRIMIPHOS-METHYL: TOXICOLOGY CHAPTER
OF THE REGISTRATION ELIGIBILITY DOCUMENT"**

Dated May 18, 1998

Health Effects Division

I. HAZARD CHARACTERIZATION

This section incorrectly states that females are more susceptible than males. In the chronic toxicity/oncogenicity study in mice, males are clearly more susceptible to clinical signs of toxicity and cholinesterase inhibition than females.

A. ACUTE TOXICITY

This section should also include the results of studies with technical grade material.

Table 1. Toxicology Profile for Pirimiphos-methyl

81-7 Acute delayed neurotoxicity - hen

A delayed neurotoxicity study in hen, MRID 00080721 has already been submitted to the Agency. Additionally, another acute delayed neurotoxicity study with pirimiphos-methyl has been published (Lock and Johnson, 1990) and is to be submitted with the FQPA document. The time table for this submission is to be determined by December 31, 1998.

E. NEUROTOXICITY

An acute delayed neurotoxicity study with pirimiphos-methyl has been published (Lock and Johnson, 1990) and is to be submitted with the FQPA document. The time table for this submission is to be determined by December 31, 1998.

USAGE INFORMATION FOR PIRIMIPHOS METHYL
Actellic 5E on Stored Corn and Sorghum Grain
Nu-Gro Insecticide on Bagged Seed Corn and Sorghum

1. Percent/or Amount of each grain/seed crop treated

Corn Grain Treated	714,960,000 lbs	0.15% of total crop
Sorghum Grain Treated	219,630,000 lbs	0.54% of total crop
Corn Seed Treated	69,014,550 lbs	0.014% of total crop
Sorghum Seed Treated	65,583,000 lbs	0.16% of total crop

2. Range of Active Ingredient Used per Application per Ton of Grain/Seed (1993 data)

Corn Grain	0.012 lbs a.i./ton	0.016 lbs a.i./ton
Sorghum Grain	0.012 lbs a.i./ton	0.016 lbs a.i./ton
Corn Seed		0.016 lbs a.i./ton
Sorghum Seed		0.016 lbs a.i./ton

(Assumes a rate of 9.3 oz product per 60,000 lbs of grain will be used for 12 month control and a rate of 12.3 oz product will be used for 18 month control)

3. Total Gallons Product and Pounds Active Ingredient (Pirimiphos Methyl) Applied per Year by Crop and Use (1993 data)

Corn Grain	1145.06 gallons	5725.3 lbs a.i.
Sorghum Grain	351.75 gallons	1758.75 lbs a.i.
Corn Seed	110 gallons	550 lbs a.i.
Sorghum Seed	105 gallons	525 lbs a.i.

USAGE INFORMATION FOR PIRIMIPHOS METHYL
Actellic 5E on Stored Corn and Sorghum Grain
Nu-Gro Insecticide on Bagged Seed Corn and Sorghum
(Supporting Calculations)

1992 Crop Production (USDA Agricultural Statistical Services)

Corn for grain or seed:	4.88×10^{11} lbs
Sorghum for grain or seed:	4.1×10^{10} lbs

Percent of Crop Treated with Pirimiphos-Methyl
Based on 1993 sales of Actellic 5E sold for stored grain use

Corn:

1,145.06 gallons sold (128 oz./gal) = 146,567.68 oz sold = 5725.3 lbs a.i. sold
12.3 oz used to treat 60,000 lbs of grain = 0.016 lbs a.i./ton
146,567.68 oz sold , 12.3 oz per treatment = 11,916.07154 treatments
11,916 treatments x 60,000 lbs = 714,960,000 lbs treated
treated grain , crop production =
 $714,960,000 , 4.88 \times 10^{11} = 0.01465$
 $0.01465 \times 100 = 0.1465 = 0.15\%$ of crop treated

Sorghum:

351.75 gallons sold (128 oz/gal) = 45,024 oz sold = 1758.75 lbs a.i. sold
12.3 oz used to treat 60,000 lbs of grain = 0.016 lbs a.i./ton
45,024 oz sold , 12.3 oz per treatment = 3,660.487805 treatments
3,660.5 treatments x 60,000 lbs = 219,630,000 lbs treated
treated grain , crop production =
 $219,630,000 , 4.1 \times 10^{10} = 0.005356829$
 $0.0053568 \times 100 = 0.53568 = 0.54\%$ of crop treated

Based on 1993 sales of Nu-Gro Insecticide S.P. sold for bulk/bagged seed use

Corn:

1,380,291 bags @ 50 lbs per bag = 69,014,550 lbs of treated seed. = 550 lbs a.i. sold
9.3 oz formulated product is used to treat 60,000 lbs seed = 0.012 lb a.i./ton
treated seed , crop production =
 $69,014,550 , 4.88 \times 10^{11} = 0.00014142$
 $0.00014142 \times 100 = 0.014142 = 0.014\%$ of crop treated

Sorghum:

1,311,680 bags @ 50 lbs per bag = 65,583,000 lbs of treated seed = 525 lbs a.i. sold
9.3 oz formulated product is used to treat 60,000 lbs seed = 0.012 lb a.i./ton
treated seed , crop production =
 $65,583,000 , 4.1 \times 10^{10} = 0.00159959$
 $0.00159959 \times 100 = 0.159959 = 0.16\%$ of crop treated

ACTELLIC 5E (Pirimiphos Methyl a.i.) ADMIXTURE VS BIN SPRAY TREATMENTS

1. Comparison of Amount of Product Used

Admixture:	12.3 oz/60,000 lbs grain	217.94 grams/60,000 lbs grain
Bin Spray:	2.6 oz/60,000 lbs grain	32.45 grams/60,000 lbs grain

Using these figures, the bin spray uses approximately 15% as much a.i. as does the admixture. $(32.45/217.94) \times 100 = 15.36\%$. This corresponds to an 84.64% reduction of a.i. between admixture and the bin spray.

2. Comparison of Anticipated Residues of Pirimiphos Methyl

Admixture

Based on the maximum labeled application rate of 12.3 oz Actellic 5E (217.94 g a.i.) per 60,000 lbs. of corn/sorghum grain:

$$217.94 \text{ g} / 453.6 \text{ g/lb} \times 60,000 \text{ lb} \times 10^6 \mu\text{g/g} = 8.0078 \text{ ppm pirimiphos methyl}$$

Proposed Bin Spray

Based on the proposed bin disinfestation application rate of 2.6 oz Actellic 5E per 1000 ft² of bin surface area:

Ø A bin of dimensions 11' x 11' x 11' would have 11' x 11' x 6 sides or 726 ft² surface area

Ø At the proposed label rate of 2.6 fluid ounces product per 1000 ft², the amount of Actellic 5E applied to this bin would be:

$$2.6 \text{ fl oz product} \times 726 \text{ ft}^2 / 1000 \text{ ft}^2 = 1.8876 \text{ fl oz product} = 33.4459 \text{ g a.i.}$$

Ø This bin would contain 1331 ft³ of grain, or effectively 30 tons (60,000 pounds) of grain, based on 1.25 ft³ / bushel x 1071 bushels/60,000 pounds.

Therefore, if all the a.i. is released from the walls and transferred uniformly to the stored grain, the maximum theoretical residue in or on the grain would be:

$$33.4459 \text{ g a.i.} / 60,000 \text{ lbs} \times 453.6 \text{ g/lb} \times 10^6 \mu\text{g/g} = 1.22 \text{ ppm pirimiphos methyl.}$$